

Reviewer Checklist

Analyst Comments for the Reviewer:

Principal Investigator:

NEW: PI's Email Address:

NEW: PI's Phone Number (from campus locator):

Study Title:

Study Number:

Submission Components

CHR Staff use only - Check here to get the Exempt Regulatory Determinations into the checklist:

- This research qualifies as Exempt

Approved Research with Proposed Changes

The proposed changes constitute:

- Minor change to approved research
 - Major modification
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- The approval of this modification is for one subject only.
 - This approval is to follow a subject or subject's partner who became pregnant on study. The research with the subject or subject's partner who became pregnant on study meets all of the conditions of 45 CFR 46.204 for the involvement of pregnant women or fetuses.

Does this modification impact or change the regulatory determinations (a 'Yes' will take you through all of the relevant determination sections):

Yes No

Device and Drug Determinations

Device Determination Guidelines (Click the [orange Help bubble](#) for criteria)

- The device as used in this study qualifies as a Non-Significant Risk (NSR) device under 21 CFR 812 based on the information provided with the IRB application.
- The IRB has determined that the device used in this study is IDE Exempt (21 CFR 812) based on the information provided to the IRB.
- The IRB has determined that the device used in this study is a Significant Risk (SR) device (21 CFR 812.3) based on the information provided to the IRB. An IDE or HDE has been granted by the FDA.

- The IRB Committee agreed that an IND was not needed for the use of the drug/supplement in this study.

Inclusion of Children

This research satisfies the following condition(s) for the involvement of children:

- 45 CFR 46.404, 21 CFR 50.51: Research not involving greater than minimal risk.
- 45 CFR 46.405, 21 CFR 50.52: Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.
- 45 CFR 46.406, 21 CFR 50.53: Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition. The plan for obtaining permission and/or assent is acceptable.
- 45 CFR 46.407, 21 CFR 50.54: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. Additional review of the research will be necessary before the research may begin.
- Wards of the state may be enrolled with permission of their legal guardian.
- Because the adolescents being enrolled in this study are legally entitled to consent to the treatments and procedures involved in the study, Subpart D of 45 CFR 46 does not apply. Parental consent is not required.

Parental Permission and Assent:

- The permission of one parent or guardian is sufficient.
- Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.
- The requirements for permission by parents or guardians is waived under 45 CFR 46.408(c) because the research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects.
- The assent of the children will be obtained.

Inclusion of Pregnant Women, Fetuses and/or Neonates

- The research meets all of the conditions of 45 CFR 46.204 for the involvement of pregnant women or fetuses.
- The research meets conditions of 45 CFR 46.205 for the involvement of neonates.
- The research meets conditions of 45 CFR 46.206 for research involving, after delivery, the placenta, the dead fetus or fetal material.
- The research meets conditions of 45 CFR 46.207: Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates.

Inclusion of Prisoners

The research meets all conditions of 45 CFR 305(a), and is permissible under the following category:

- 45 CFR 46.306(a)(2)(i) Study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
- 45 CFR 46.306(a)(2)(ii) Study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects.
- 45 CFR 46.306(a)(2)(iii) Research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults).
- 45 CFR 46.306(a)(2)(iv) Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject.
- HHS Secretarial Waiver (68 FR 36929, 6/20/03) Epidemiological research with prisoners: The research must have as its sole purpose (i) to describe the prevalence or incidence of a disease by identifying all cases, or (ii) to study potential risk factor associations for a disease. The study poses no more than minimal risk and presents no more than an inconvenience to the prisoner subjects, and prisoners are not the focus of the research.

HIPAA

HIPAA Determinations

This study involves the use of a limited data set. The only allowable health information identifiers are:

- 5 digit zip code (the 4 digit extension is not allowed)
- dates of birth, death, admission, discharge
- all geographic subdivisions other than street address

- The IRB has approved access to health records provided as a Limited Data Set. In this case, neither HIPAA authorization nor waiver are required. If the researchers determine that any of the other 18 HIPAA identifiers are needed, they must submit a modification to request a Waiver of HIPAA Authorization.
- The IRB has approved access to a subset of identifiable patient data for data validation preparatory to research. The IRB has approved use of a Limited Data Set (LDS) for the study.

- Individual Research HIPAA Authorization is required of all subjects. Use the Permission to Use Personal Health Information for Research form.
- Individual Research HIPAA Authorization is required for one or more subject groups. Use the Permission to Use Personal Health Information for Research form.
- No PHI is used after recruitment and therefore individual Research HIPAA Authorization is not required for participation in the study.
- This research is not subject to HIPAA rules.
- HIPAA rules do not apply to one or more subject groups.

- The requirement for individual Research HIPAA Authorization is waived for all subjects. The use or disclosure of the requested information does not adversely affect the rights and welfare of the individuals and involves no more than a minimal risk to their privacy based on, at least, the presence of the following elements:
- The requirement for individual Research HIPAA Authorization is waived for some subjects, as detailed in the application. The use or disclosure of the requested information does not adversely affect the rights and welfare of the individuals and involves no more than a minimal risk to their privacy based on, at least, the presence of the following elements:

- (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or if such retention is otherwise required by law;
- (3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule;
- (4) the research could not practicably be conducted without the waiver; and (5) the research could not practicably be conducted without access to and use of the requested information.

- For studies involving the SF VAMC, a waiver of the requirement to obtain individual HIPAA Authorization has been granted. The research does not involve access to VA medical records and involves no more than self-report of personal health information.

HIPAA and Consent Waiver for Recruitment Procedures

- A waiver of HIPAA Authorization and consent is acceptable for the recruitment procedures to identify potential subjects. The recruitment procedures involve routine review of medical or other records, do not adversely affect the rights and welfare of the individuals, and pose minimal risk to their privacy, based on, at least, the presence of the following elements:
- (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, or a health or research justification for retaining the identifiers was provided or such retention is otherwise required by law;
- (3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule;
- (4) the research could not practicably be conducted without the waiver; and (5) the study recruitment could not practicably be conducted without access to and use of the requested information. Study participants will sign a consent form prior to participation in the study.

Waiver of Documentation of Informed Consent

- A waiver of the requirement to obtain a signed consent form is acceptable for this study because, as detailed in the application, the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
- A waiver of the requirement to obtain a signed consent form is acceptable for this study because, as detailed in the application, the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- The waiver applies to all subjects.
- The waiver applies to some subjects, as detailed in the application.
- A waiver is not acceptable. Signed consent must be obtained.

Waiver or Alteration of Informed Consent

- A waiver or alteration of informed consent is acceptable because, as detailed in the application: (1) the research involves no more than minimal risk to the subjects; (2) the research could not practicably be carried out without the waiver or alteration; (3) if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format (OHRP requirement only); (4) the waiver or alteration will not adversely affect the rights and welfare of the subjects; and (5) whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- The waiver or alteration of informed consent applies to all subjects.
- The waiver or alteration of informed consent applies to some subjects, as detailed in the application.
- A waiver or alteration of informed consent is not acceptable for this study.
- This study has been granted an alteration of the requirements to obtain informed consent. Some details of the study objectives will be withheld from participants at the time of consent. This waiver is acceptable because the study objectives cannot be met without the alteration and the IRB has agreed that the rights and welfare of the subjects will not be negatively impacted by the granting of this waiver.
- The participants will be debriefed after the study intervention and given the option to have their data destroyed.
- The participants will be debriefed after the study intervention, if appropriate, and given the option to have their data destroyed.
- The participants will not be debriefed. The information shared during debriefing could contaminate the potential subject pool and invalidate results.

Exception from Informed Consent for Research in an Emergency Setting

Research in an emergency setting:

- It is appropriate to conduct the research in an emergency setting.
 - It is appropriate to waive consent at the time of enrollment, if necessary.
 - The plans for ongoing attempts at obtaining informed consent are adequate.
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- The IRB has granted an alteration of consent for this minimal risk research conducted in an emergency setting under 45 CFR 46.116: Consent may be deferred if surrogate consent is needed and participants will be asked to provide consent once they have regained consciousness or are stable enough to be approached for research participation.

Surrogate Consent

- The plans for obtaining informed consent from legally authorized representatives are acceptable and are consistent with California law and UC guidance.

Post-Approval Event Expedited Review

IRB Unanticipated Problem Determination (specify comments in the Review Comment section):

- Not an Unanticipated Problem (submission can be acknowledged and closed)
- Possibly an Unanticipated Problem (send to full committee to determine)
- Unanticipated Problem (send to full committee to confirm determination)

IRB Serious and/or Continuing Noncompliance Determination (specify comments in the Review Comment section):

- Not Serious and/or Continuing Noncompliance (submission can be acknowledged and closed)
- Possibly Serious and/or Continuing Noncompliance (send to full committee to determine)
- General Noncompliance (submission will be given determination of noncompliance and closed)

Post-Approval Event Committee Review

Full Committee Determinations (check all that apply and specify comments in the Reviewer Comment section):

- Unanticipated Problem
- Not an Unanticipated Problem
- Serious Noncompliance
- Not Serious Noncompliance
- Continuing Noncompliance
- Not Continuing Noncompliance

- Noncompliance

Exempt Research

This research qualifies as exempt under the following category:

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research using educational tests, survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers; and (ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation.
- (3) Research using educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- The requirement for individual HIPAA authorization is waived for all subjects. The use or disclosure of the requested information does not adversely affect the rights and welfare of the individuals and involves no more than a minimal risk to their privacy based on, at least, the presence of the following elements:
- (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or if such retention is otherwise required by law;
- (3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule;
- (4) the research could not practicably be conducted without the waiver; and (5) the research could not practicably be conducted without access to and use of the requested information.

- A waiver of HIPAA Authorization is acceptable for the recruitment procedures to identify potential subjects. The recruitment procedures involve routine review of medical or other records, do not adversely affect the rights and welfare of the individuals, and pose minimal risk to their privacy, based on, at least, the presence of the following elements:

- (1) an adequate plan to protect the identifiers from improper use and disclosure; (2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, or a health or research justification for retaining the identifiers was provided or such retention is otherwise required by law;
- (3) adequate written assurances that the requested information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule;
- (4) the research could not practicably be conducted without the waiver; and (5) the research could not practicably be conducted without access to and use of the requested information.

Expedited Review Categories

This submission was eligible for expedited review as:

- Minor changes in previously approved research
- Category 1(a): Clinical studies of drugs for which an investigational new drug application is not required
- Category 1(b): Clinical studies of medical devices for which an investigational device exemption application is not required or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling
- Category 2: Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture (healthy non pregnant adults 110lbs or more, no more than 550mL in 8 weeks and no collection more than 2x a week OR other adults and children not exceeding the lesser of 50 ml or 3 ml per kg in an 8 week period and no collection more than 2x a week)
- Category 3: Prospective collection of biological specimens for research purposes by noninvasive means
- Category 4: Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing
- Category 5: Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis)
- Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes
- Category 7: Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
- Category 8(a): Renewal of inactive research protocols or protocols that are essentially complete: where research is permanently closed to enrollment; all subjects have completed research-related interventions; and research remains open only for long-term follow-up of subjects
- Category 8(b): Renewal of inactive research protocols or protocols that are essentially complete: where no subjects have been enrolled and no additional risks have been identified

- Category 8(c): Renewal of inactive research protocols or protocols that are essentially complete: where the remaining research activities are limited to data analysis
- Category 9: Renewal of other minimal risk research protocols: Continuing review of research, not conducted under an IND or IDE where categories 2 through 8 do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified

Reviewer Recommendations

Reviewer Comments:

Rank	Reference	Item Number(or name)
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No Comments have been entered.

Criteria for Approval of Research

- Risks to subjects are minimized;
- Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result;
- Selection of subjects is equitable;
- Informed consent will be sought from each prospective subject or the subject's legally authorized representative, and appropriately documented;
- Where appropriate, the research plan adequately provides for monitoring the data collected to ensure the safety of subjects;
- Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data;
- Appropriate additional safeguards are included to protect vulnerable subjects; and
- Where the study involves children, the research complies with 21 CFR part 50, Subpart D.

Does this study meet all of the required criteria for approval:

Yes No

Criteria for Approving Research During Continuing Review

Based upon information provided in the Continuing Review Form, including any reportable events, unanticipated problems, complaints, and/or changes that are now proposed or have been approved during the last approval cycle, are the risks to subjects

(1) minimized, and

(2) still reasonable in relation to anticipated benefits, if any, to subjects and the importance of the knowledge that may be expected to result:

Yes No

Recommended outcome:

- Accepted/Acknowledged/Closed
- Approve
- Revisions required (Response reviewed by Chair or designated reviewer)
- Return for additional information (Response reviewed by Full Committee)
- Forward to Full Committee (Required for possible unanticipated problems and noncompliance)

Data analysis phase:

- This study is in data analysis and involves no greater than minimal risk for the population being studied.

- The full board determined that the research poses no greater than minimal risk and is eligible for expedited review in the future under category #9.

Review Period:

Other Assigned Reviewers and Complete the Review:

Reviewer Role	Reviewer	Completed
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